Supplementary Online Content

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eAppendix. Trial Protocol: Compensation for Transport Costs and Lost Wages Associated With VMMC Uptake: an Intervention to Increase VMMC Demand Among Older Men in Nyanza Province

This supplementary material has been provided by the authors to give readers additional information about their work.

Compensation for transport costs and lost wages associated with VMMC uptake: an intervention to increase VMMC demand among older men in Nyanza Province

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Abstract

Background: Kenya has had the most success among countries in sub-Saharan Africa in scaling-up voluntary medical male circumcision (VMMC) services, but challenges remain in reaching men between the ages of 25-49 years. Two important barriers to circumcision that have emerged from qualitative work in Nyanza Province are the time and transport costs of accessing VMMC services and the hesitation to take time off work on the day of the procedure and during the post-procedure healing period (usually around 2-3 days). Men have indicated that they are concerned about providing for their families, in particular making sure they can feed their families while they are unable to work during the healing period.

Primary Objective: To evaluate the effect of providing conditional economic compensation for transport costs and low wages on the uptake of voluntary medical male circumcision (VMMC). The compensation will be in the form of a refreshment for the control group or food vouchers for the intervention groups, the amounts of which will be individually randomized to one of three amounts: 200 KES, 700 KES, 1,200 KES

Secondary Objectives: Assessperceptions of the intervention among men and their female partners through qualitative in-depth interviews. The qualitative assessment will improve our understanding of the role that the intervention played in influencing men's circumcision uptake decisions.

Design: Randomized controlled trial

Population: Men between 25 and 49 in Nyando District, Nyanza Province, Kenya and female partners of the men

Study Duration: February 2012 through February 2013

Primary Endpoint: Uptake of VMMC services within 2 months after enrollment in the study

Secondary Endpoints: (1) A list of perceptions among male study participants about the food voucher intervention and their role in decision making about uptake of VMMC; (2) A list of perceptions among female partners of study participants about the food vouchers and their role in men's decision-making.

Key variables: Intervention assignment
Socio-economic characteristics
Individuals' beliefs about benefits of MC
Time and risk preferences

Methods of analysis: Comparison of means between intervention groups and control group, as well as regression analysis that controls for baseline socio-economic characteristics.

List of Acronyms

AIDS	Acquired Immunodeficiency Syndrome
BMGF	Bill and Melinda Gates Foundation
CPC	Carolina Population Center
GoK	Government of Kenya
HIV	Human Immunodeficiency Virus
IRDO	Impact Research and Development Organization
KES	Kenya Shillings
NIH	National Institutes of Health
RCT	Randomized controlled trial
VMMC	Voluntary Medical Male Circumcision
UNAIDS	Joint United Nations Program on HIV/AIDS
WHO	World Health Organization
PEPFAR	United States President's Emergency Plan for AIDS Relief

1 INTRODUCTION

1.1 Background

Sub-Saharan Africa, the region most heavily affected by HIV/AIDS, accounts for 68% and 90% of the world's adult and childhood HIV cases, respectively. Despite large-scale and varied HIV prevention efforts, incidence rates in the region remain high, with an estimated 1.9 million (1.6-2.2 million) adults and children newly infected with HIV in 2008. The identification of scalable and effective behavioral and bio-medical HIV prevention interventions has thus become a major priority in many HIV-affected countries.

Encouragingly, three randomized controlled trials (RCTs) conducted recently have established that medically-performed circumcision of adult males significantly reduces their risk of acquiring HIV. Studies in South Africa, Kenya and Uganda have shown that men who had been assigned to the circumcision group had 60% (South Africa), 53% (Kenya), and 51% (Uganda) lower incidence of HIV infection than men assigned to the control group that was circumcised after the trials were complete.[1-3]

Based on this RCT evidence, WHO, UNAIDS and PEPFAR recommended the expansion of voluntary medical male circumcision (VMMC) services for HIV prevention in countries with high HIV prevalence and low circumcision prevalence.[4, 5] A number of countries have recently begun to implement MC scale-up plans, with ambitions to reach a high-level of MC coverage within a short time span. Estimates suggest that by scaling up VMMC to reach 80% of males ages 15-49 in five years – i.e. performing 20.3 million circumcisions – and maintaining such coverage until 2025, 3.4 million new HIV infections could be averted by 2025 with total cost savings of nearly US$20 billion.[6] Although countries have set targets of increasing circumcision prevalence to 80%, progress has been highly uneven even though it has been found to be acceptable in many countries.[7] In Nyanza Province, nearly 430,000 men have been circumcised from October 2008 to March 2012 and 66% of the target for the Province has been met.[8] But in other countries less than 10% of their objectives have been achieved.[6]Understanding how elements of supply and demand affect uptake of circumcision can play an important role in achieving rapid scale-up of VMMC.

1.2 Uptake of MC in Kenya

Kenya is experiencing a generalized HIV epidemic, with an overall prevalence of 6.4% among adults.[9] According to the 2008-2009 Kenya Demographic and Health Survey, the lowest age-specific HIV prevalence is observed among 15-19 year old men (0.7%) with prevalence rising rapidly thereafter to a peak of 10.4% among men 35-39. The largest increase in HIV prevalence among men occurs between ages 20-29, indicating that this is a key age group to target with HIV prevention efforts. Nyanza Province has both the highest HIV prevalence (13.9%) and the lowest prevalence of male circumcision (44.8%) in Kenya. The Luo, the predominant ethnic group in Nyanza, have the highest HIV prevalence of any ethnic group (17.1%) and are a traditionally non-circumcising group, which likely contributes to the high HIV prevalence.

In November 2008, the Government of Kenya (GoK) launched a National Program of Voluntary Medical Male Circumcision that aimed to circumcise 860,000 men ages 15-49 years by 2013.[8] In Nyanza Province, the current target is to increase the proportion of men circumcised from 47% to 80%—or to perform 426,500 circumcisions over a four-year period. Kenya has had notable success with scale up, reaching 477,000 men or approximately 55% of the national target by November 2012.[10] From 2010 to 2012, Kenya's Rapid Results Initiatives (RRIs), the intensive programmatic efforts to provide VMMC services during school holidays at the end of the year, increased the numbers of males over the age of 15 coming for VMMC; however, the number of men above the age of 24 who have been circumcised remains lower than desired with only approximately 10% of men ages 25 and above circumcised in Nyanza.[6, 8, 9, 11] Given the higher risk of acquiring HIV faced by men in this age group, increasing VMMC uptake is likely to have the most immediate impact on population-level HIV incidence in Nyanza. In order to increase uptake, it is important to identify men's barriers to seeking VMMC and potential interventions to address those barriers.[6]Based on recent findings about the barriers and facilitators to uptake of VMMC services in Kenya, the aim of this study is to undertake a randomized controlled trial that

will test whether offering compensation for costs of transportation and time lost-at-work will increase uptake of VMMC services among men between 25-49 years of age.

2 RATIONALE

2.1 Effectiveness of Male Circumcision to Prevent HIV

Observational studies have suggested that male circumcision has a protective effect for men exposed to HIV. In 2006, randomized controlled trials confirmed that male circumcision is associated with 60% reduction in HIV risk and served as an impetus for promoting circumcision as a key strategy for HIV prevention.

2.2 Barriers to Demand for Voluntary Medical Male Circumcision

A recurring concern in public health is that beneficial health interventions are not taken up by individuals, even when information about these benefits is made widely available. Now that the efficacy of male circumcision is clear, the research and policy focus has shifted towards the challenges in scaling-up VMMC services. Issues of access and uptake arecritical in determining the population-level effectiveness of male circumcision. Worldwide, the practice of male circumcision is known to be driven by religious, cultural and medical reasons.Several studies have reported high levels of acceptability of male circumcision in Kenya.[7] But in spite of large HIV prevention benefits, in practice a number of barriers – cultural, religious, behavioral, and economic – are likely to limit uptake.

Understanding how elements of supply and demand affect uptake of adult male circumcision can play an important role in achieving rapid scale-up of VMMC in sub-Saharan Africa and contribute to success of HIV prevention efforts. Previous research has identified facilitators and barriers to VMMC uptake at individual, interpersonal, health systems and societal levels. Across existing research studies, the most consistent barriers to uptake at the individual level include: cost (including financial and opportunity costs such as lost income due to time away from work) [7, 11-13], fear of pain[7, 12, 14, 15], concern about safety during surgery and adverse events following the procedure[11], and the post-procedure abstinence and healing period.[16]

Although Kenya has had the most success among countries in sub-Saharan Africa in scaling-up VMMC services, there have been challenges in reaching older men. Among older men, two important barriers to circumcision that have emerged from qualitative work in the Nyanza Province [16, 17] are the time and transport costs of accessing VMMC services and the hesitation to take time off work on the day of the procedure and during the post-procedure healing period (usually around 1-3 days). Men have indicated that they are concerned about providing for their families, in particular making sure they can feed their families while they are unable to work during the critical healing period of anywhere between 1-3 days after the procedure.

The lower-than-desired uptake of VMMC among older men is motivating the GoK and implementing partners to develop new strategies to increase the numbers of men in this age group seeking VMMC services. Presently, national and provincial VMMC task forces and implementing partners are piloting new approaches to recruit older men for services such as partnering with large employers in the region, utilizing older circumcised men as community mobilizers and providing incentives for these community mobilizers when older men present at VMMC facilities for information.[8, 11]Identifying effective ways to increase uptake among this population remains a priority in Kenya and other countries.

2.3 The use of conditional economic compensation to achieve behavior change

Compensating men for the out-of-pocket expenses and other financial costs associated with undergoing VMMC would help eliminate some of the barriers to uptake of VMMC. If the amounts are chosen correctly the compensation could make the procedure have zero financial cost, but not provide an excessive incentive to get circumcised.Addressing the economic barriers to male circumcision by covering out-of-pocket expenses and other financial costs associated with undergoing VMMC would build on the success of programs that have used monetary or non-monetary compensation to achieve behavior change in other settings[18-20]. In the past twenty years, these programs – sometimesreferred to as conditional

cash transfer (CCT) programs when the compensation is in the form of cash – have grown in number and have been used to improve various health behaviors. Typically, CCTs provide monetary transfers to households on the condition that they comply with a set of behavioral requirements. These requirements are typically linked to attendance for preventive interventions at primary health care facilities and educational enrollment for children. The economic rationale for CCT or other forms of conditional economic compensation programs lies in the recognition that some individuals or households may lack the resources to uptake services. By providing compensation if the services are accessed (i.e. the conditions are met), the CCT intervention can overcome the economic barriers to accessing care. Such programs also have a behavioral rationale that is based on the theory of present-biased preferences, whereby individuals' behaviors are driven by immediate costs and benefits as opposed to future costs and benefits.[21, 22]As such, conditional economic compensationmay be an effective strategy for increasing circumcision prevalence among older men, and it would be an intervention that has the potential to be both low-cost (because the focus would be centered on the current population of older men) and scalable.

2.4 Increasing VMMC uptake through compensation for lost work and transport costs

In the eight districts where IRDO is the primary provider of VMMC services, data from 2008-2011 indicate that only 5-20% of men ages 25-49 have been circumcised. Uptake of VMMC services among younger men (15-24 years) has been considerably higher, however. New strategies to make VMMC appeal to older men must therefore be conceived and evaluated. Two important barriers for older men are: (a) the transportation costs to VMMC sites; and (b) the lost wages because of time away from work in the days following the procedure. The second barrier is not as prominent for younger men, particularly those who are between 15-20 years of age. Both barriers are especially pronounced among men whose opportunity costs of time are higher and whose work abilities are likely to be reduced during the healing period following the circumcision procedure – i.e. fishermen, transport workers, or casual laborers. Particularly for men who work in the informal sector, one concern is that they would not be able to provide food for their families. At a stakeholders workshop organized by FHI 360 in Nyanza Province in February 2012, compensation for lost work and transport costs was suggested as an intervention that should be implemented among older men. As a result, in collaboration with IRDO we propose to evaluate whether providing food vouchers to those who come for VMMC increases its uptake.

2.5 Study Generalizability

This study will randomize the intervention in a rural population of older men (defined as men between the ages of 25 and 49) who serve as the target for increasing uptake of male circumcision services. Study results should be useful for informing policy and strategies toincrease uptake of VMMC among men 25 - 49, who have proven more reluctant to seek circumcision, in other areas of Kenya and beyond.

3 STUDY OBJECTIVES AND HYPOTHESIS

The purpose of this study is to evaluatewhether offering compensation in the form of food vouchers to older men conditional on their coming for medical male circumcision will increase demand for and uptake of circumcision services. The proposed project will use a randomized design to test whether conditional in-kind compensation for transport costs and lost time at work can increase the uptake of VMMC among uncircumcised Kenyan men aged 25-49 years.

3.1 Specific Objectives

Objective 1: Randomized provision of food vouchers conditional on coming for VMMC and evaluation of its effects on VMMC uptake. We hypothesize that a higher proportion of the men who receive non-transferable food vouchers worth either KES 700 (US$8.75) or KES 1200 (US$15)will seekcircumcision compared to men who receive food vouchers worth KES 200 (US$2.50) or no food vouchers at all (just a refreshment).

Objective 2: Assessperceptions of the intervention among men and their female partners through qualitative in-depth interviews. The qualitative assessment will improve our understanding of the role that the intervention played in influencing men's circumcision uptake decisions.

3.2 Study Outcome Measures

The primary outcome for the study will be uptake of male circumcision within 2 months after men were given the opportunity to receive a food voucher. To verify that vouchers are distributed only to those who undergo male circumcision, we will establish a linkage system in which we record the unique offer identification number assigned to men (a) when randomization takes place at the time of study enrollment; and (b) when men come to the VMMC clinics and present the scratch cards given to them along with certification by the health worker at the clinics.

Trained research assistants will be based at the VMMC clinics that are managed by IRDO. The research assistants will be responsible for distribution of the food vouchers to men who were enrolled in the study and chose to get circumcised. The research assistants will record the voucher number and the client's name and study ID number before giving him the food voucher.

4 STUDY DESIGN

4.1 Overview of Study Design

The proposed study will used a randomized design to test whether offering compensation to older men conditional on their coming for circumcision can increase uptake of VMMC services. Participants will be visited at their homes, informed about the intervention, and then randomized to receive food voucher *offers* of KES 200 (transport cost intervention), KES 700 (intervention 1), KES 1200 (intervention 2), or a refreshment (i.e. no opportunity to receive food vouchers). The food vouchers will be offered to the men if they undergo male circumcision at one of the IRDO clinics in the study area within 2 months after randomization.The men will need to come to one of the IRDO clinics in Nyando District and the vouchers will be given after the circumcision procedure. The opportunity to get food vouchers will not be transferable to other men who want to get circumcised. Research assistants stationed at the IRDO clinics will record the study identification numbers of participants who come to clinic to seek circumcision and will also be the ones who distribute the food vouchers. Further details of the study are outlined in the protocol in Section 5. The food vouchers can be used at a specified network of shops (*dukas*)in Nyando District, and they will retain their value for up to 1 month from the time that they receive the voucher. The shops will be visited by the study team and informed about the voucher scheme. Participating shops will be told that at the end of every week, they will be visited by the study team and reimbursed the value of the vouchers that they receivedfrom customers in the past week.Post-intervention qualitative interviews will be conducted with a sample of study participants and their partners in order to learn about their perceptions of the intervention, specifically if they perceived the intervention as coercive.

4.2 Study Setting

This intervention will be implemented in Nyando District, located in Nyanza Province, about 25 kilometers from Kisumu. Nyando District consists of 5 Divisions, 28 Locations and 76 Sub-locations and has a population of 26,070 men between the ages of 25-49. By 2011, IRDO had circumcised 3,102 men ≥25 yearsthere (coverage of 12%). We have chosen Nyando District because of the low circumcision prevalence and because the District has a diverse range of occupations including fishing, plantation work, casual labor and a large informal sector. The district therefore provides a setting to evaluate the appropriateness of the proposed intervention across various occupations.

4.3 Study Population

The study will aim to enroll 1,500 uncircumcised men of eligible ages (see sample size calculations below). The 76 Sub-locations in Nyando District will be stratified in one of three clusters (beach, urban, or rural). We will then randomly select Sub-locations within each of the three strata using population weights. Within selected Sub-locations, household enumeration will be undertaken to obtain the name

and age of men who reside in the households. After completion of the household enumeration, 2,100 men of eligible ages will be randomly selected for household visits. Only men who report that they are not circumcisedwill be enrolled in the study and given the opportunity to receive the conditional compensation.

4.4 Inclusion Criteria

Eligible participants will be uncircumcised males aged 25-49 and living in Nyando District with no intent to move away in the next 3 months. For this part of the study, participants must meet all of the following criteria:

1. Male
2. Are 25-49 years of age
3. Uncircumcised
4. No intent to move away from the household in next 3 months

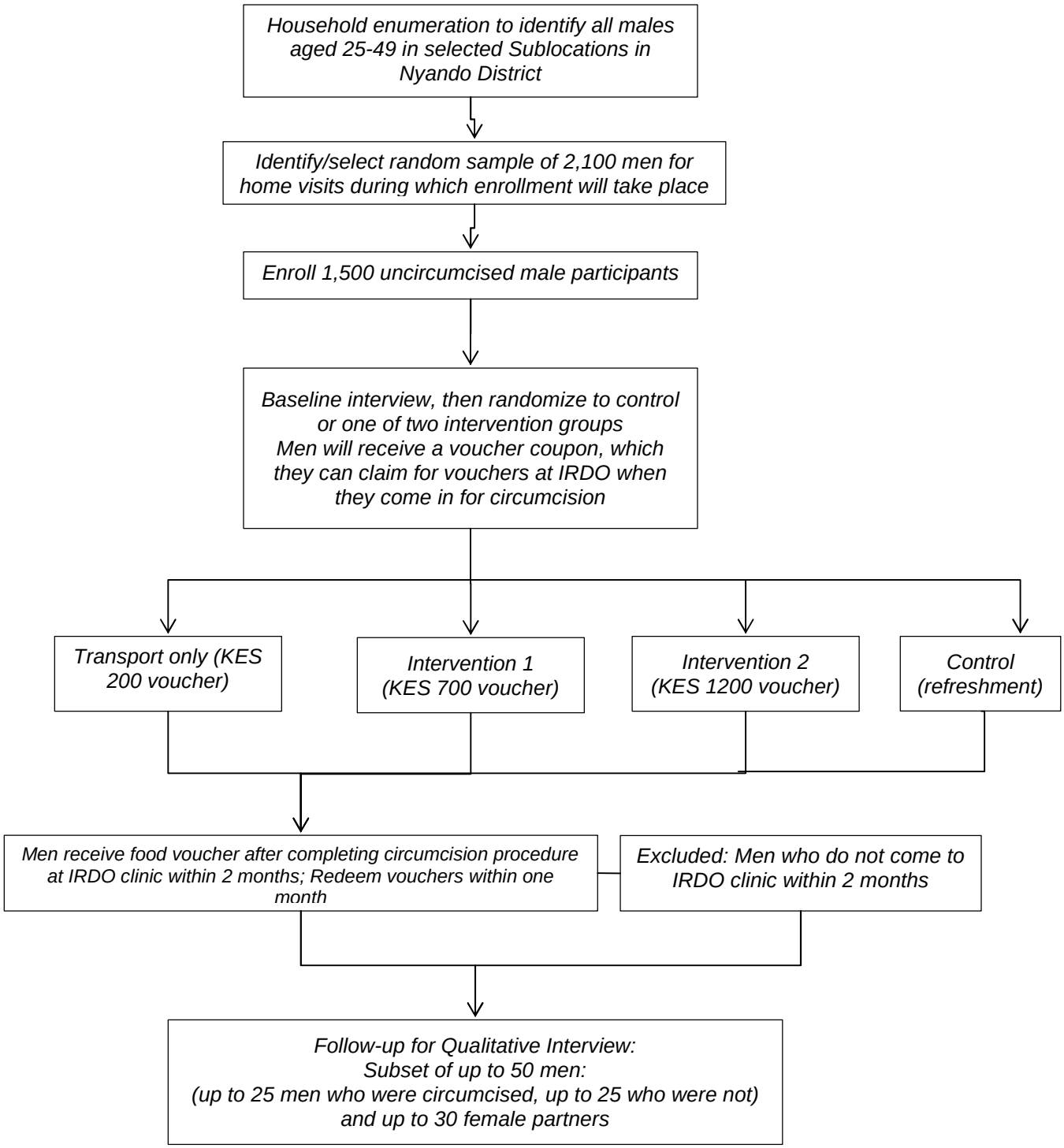
Qualitative interviews will be with up to 50 of the men enrolled in the study: up to 25 men who became circumcised and up to 25 men who were not circumcised. In addition, up to 30 female partners of men enrolled in the study will participlein in-depth interviews. .

4.5 Exclusion Criteria

Men who are already circumcisedwill not eligible for enrollment. Women will not be eligible for the intervention of the study, but a number of female partners of men will be selected for the qualitative interviews.

5 METHODOLOGY

5.1 Schematic of Voucher Protocol



5.2 Recruitment into the Study Population

The study will aim to enroll 1,500 uncircumcised men of eligible ages. Participants will be identified through a two-step process: first, sub-locations within Nyando districts will be selected across four strata (beach, urban, plantation, or subsistence farming areas) using population weights. Within each sub-location, households will be enumerated to generate a listing with the name and age of men who reside in each household and are between the ages of 25-49 years. The listing exercise will be done at each household and the respondent for the listing exercise can be any adult household member. A household enumeration form (Annex A) will be completed following oral consent. From this list of men, 2,100 men will be randomly selected for household visits, with the expectation that 12-15% of them will already be circumcised and therefore ineligible for enrollment in the study. Enrollment in the study will take place during the household visits, for men who report that they are not circumcised.

5.3 Treatment Assignment Procedure

5.3.1 Sequence generation

A block randomization scheme with block sizes of 100 will be generated. This will ensure approximately equal sample sizes and that participants and study staff cannot anticipate assignment to either group. The two intervention groups, the one transport compensation group, and the control group will be allocated in a 1:1:1:1 ratio. All study investigators and staff will be blinded to the block number, block size and sequence in the block. The treatments will be assigned via pre-prepared scratch-card that individuals will be asked to select themselves from a set of many cards.

5.3.2 Allocation Concealment

Trained research assistants will visit the 1,500 men who are selected to participate in the study. After obtaining informed consent, a brief questionnaire will be administered in which individual and household socio-economic and demographic characteristics will be obtained. The questionnaire will also elicit men's knowledge about male circumcision and all men will be told about locations where IRDO offers VMMC services. After completion of the brief questionnaire, men will be given the opportunity to take a scratch-card with a unique offer identification number and the value of the voucher they can obtain if they come for VMMC services within 2 months. One of four different values will be randomly assigned to each scratch-card.

5.3.3 Blinding

Men will be interviewed at baseline and prior to selecting their randomization scratch-card, so that interviewers cannot guide people to particular voucher values. Participants will be asked to select their own scratch-card. The scratch-card "control number", which will identify the group assignment and voucher value, will be recorded by study staff.

5.4 Baseline interview

Men who agree to participate in the study will be interviewed to obtain demographic information and sexual behavioral history. The questionnaire is included in Annex C. Following completion of the interview, each participant will be allowed to choose a scratch-card which would be his randomization assignment and voucher offer.

5.4.1 Obtaining Food Vouchers

At randomization, participants will receive a unique identification number. When they arrive at the clinic for circumcision, attendants will check the names on national identity cards to verify that the person who received the voucher offer is the same person who came in to be circumcised. If this is not possible,other information provided during the baseline interview will be used to verify the identity of the person. Food vouchers will be provided after successful completion of the circumcision procedure.

The food vouchers will be valid at *dukas* (shops) located within the district. At the beginning of the study, these shops will be visited and informed about ways to receive cash for the vouchers at the central IRDO office in Nyando District. IRDO has previously explored the feasibility of implementing the voucher scheme and found that it can be implemented in the study areas.

5.4.2 Rationale for Selecting Intervention and Control Conditions

We have selected two different food voucher amounts for the main intervention groups in order to determine what amount is likely to be necessary to fully compensate men for lost work and transport costs associated with coming for male circumcision. By having two different intervention amounts and comparing them to a control group and a group that receives compensation for transport costs only, we will learn how responsive men are as the amount of compensation varies. Men in the two main intervention groups will receive food vouchers of either KES 700 (US$8.75) or KES 1200 (US$15) if they choose to get circumcised within 2 months after enrollment. The specific amounts for each voucher were selected based on the approximate value of 3 days' worth of work (ranging from KES 300 to 1200, depending on one's occupation and nature of work) and average transportation costs to VMMC clinics in Nyando District (KES 200). Subjects randomized to transportation only group will also receive a food voucher worth KES 200 (US$2.50) if they choose to get circumcised. By comparing this group to the control group that receives no food voucher offer (refreshment only), we will determine whether providing compensation for transport costs alone results in an increase in VMMC uptake.

We believe the food voucher denominations are appropriate because they are comparable to the combined costs associated with transportation to the clinic and income loss over the 3 day recovery period. However, the specific amount of income loss associated with not working is likely to vary for each man; it can be large for men who are very productive or in high-paying occupations, or it can be small for men who are unemployed or working in low-paying occupations. Thus, the optimal amount of compensation that should be provided by a program is unknown, and a randomized trial is essential for determining which amount has the desired effect on VMMC uptake while at the same time not being coercive. Separately, a voucher of KES 200 (US$2.50) is appropriate compensation for transportation costs, since most men in this district do not have their own mode of transportation. Finally, we believe it is essential to have a control group receiving no food voucher offers (i.e. the standard of care currently) because this will allow to convincingly establish whether the provision of food vouchers, whether small or large in value, can increase VMMC uptake rates. It is important to note that the control group will not be deprived of existing VMMC services in Nyando District.

5.4.3 Circumcision Procedure

See section 6, Study Clinic Visits and Procedures.

5.4.4 Costs of Intervention

Participants who choose to get circumcised will shoulder the costs of transportation and any income loss associated with taking time off work during the 3 day recovery period after the procedure.

5.5 Qualitative interviews post-intervention

We will conduct qualitative follow-up interviews with up to 50 the enrolled participants: 25 men who got circumcised and 25 men who did not. The main objective of the qualitative interviews will be to better understand why the intervention is or is not effective. Specifically, the interviews will explore decision making around circumcision including how the food voucher affected the decision to become circumcised, female partner's perceptions of the voucher and the logistics of the intervention. When applicable or possible, up to 30 female partners of these selected men will also be interviewed to discuss the same issues. Draft interview guides for men and women are provided in Annex D. These guides will be pilot tested and updated during interview training. Final versions of guides will be submitted as an informational item. Participants will receive some refreshments as well as compensation for transport in case they have to travel to participate in the interview.

5.6 Return visits to obtain self-reported circumcision uptake

We will conduct a follow-up visit with a random sample of study participants in the control group in order to obtain a self-report of whether men sought VMMC services since the start of the study. This will be done in order to address the concern that men in the control group will not bring their scratch card when they come for VMMC services, thereby preventing us from knowing whether they became circumcised.

Study Protocol V 4.0, Last Updated April 29, 2013

6 STUDY CLINIC VISITS AND PROCEDURES

6.1 Initial clinical visit for circumcision

The primary outcome for the study will be uptake of male circumcision within 2 months of offering the opportunity to receive a food voucher. The clinic visit during which a man becomes circumcised serves as the primary outcome endpoint of this study. Men interested in undergoing MC will visit an IRDO clinic of their choice for education on male circumcision, HIV testing and counseling, booking according to the clinic schedule, and consent and performance of the procedure. Men who test HIV-positive will still be eligible for the study and they will be offered VMMC as is the case in Kenyacurrently.

6.2 Study withdrawal for participants

Participants will be free to withdraw from the study at any time by presenting to the study clinic and indicating their desire to withdraw. Reasons for study withdrawal will be ascertained. Where possible, information on study primary and secondary endpoints will be evaluated at the time of study withdrawal. No further messages will be sent, or phone calls made, to a participant who deliberately withdraws from the study.

7 STUDY ADVERSE EVENTS

We do not have obvious safety concerns in this study because it does not involve invasive procedures or collection of biological samples. This study does not seek to assess the consequences of the circumcision procedure itself, which is something that is currently monitored by the provider of the circumcision services. However, we will monitor whether there are adverse events due to the offer of food vouchers among subjects or in the study communities; these will be reported to relevant human subjects committees. For example, we will promptly file a report in case there are signs of an informal market for the food vouchers, or if participants perceive the intervention to be coercive, or if social harm is reported.

Previous work in the field and consultation with community members has confirmed that the voucher amounts are commensurate with the time lost at work resulting from the procedure and critical recovery period. After implementation of the baseline surveys, there will only be passive follow-up in the sense that we will record whether subjects came for circumcision services.

8 ETHICAL CONSIDERATIONS

8.1 Informed consent

During the enumeration of individuals residing the study communities, oral consent will be obtained. The enumeration form and the script that will be followed by research assistants are shown in Annex A. Following enumeration, men of eligible ages will be selected for the study and visited at their homes.

Before participants are enrolled in the study, they will receive a brief introduction to the study and a general overview of its aims, as outlined in the consent form (Annex B). Interviewers will be careful to impress upon participants that they may choose to decline to participate or withdraw from the study at any time. They will be asked to sign and date an informed consent form prior to enrolment and randomization. The consent forms shall describe the study procedure in the language the subject is comfortable with (English, Swahili or Dholuo). The subject will be asked to read and review the document. If a subject cannot read, the consent form will be read to them. The study will then be explained to the subject by a study staff, who will also answer any questions that arise. A copy of the informed consent document will be given to the subjects for their records.

8.2 Ethical Approval

During the early stages of the project, we will form a Community Advisory Board (CAB) in Nyando District that will bring together key stakeholders in the VMMC rollout in the district and beyond. These will include1-2 members of the Nyando District Health Management Team, 1-2 members of the Nyando District VMMC Steering Committee, a representative from each of the National and Provincial VMMC Taskforces, 2-3 selected opinion leaders, a member of 1-2 civil society organization(s), 1-2 members of the Luo Council of Elders, and 1-2 men in the target age bracket who have been circumcised. We will meet to plan how to ensure that the intervention is culturally appropriate and viewed as being useful. We will also identify potential barriers to implementation that can be addressed before we begin. Prior to implementing the intervention, the CAG will identify other key stakeholders to participate in a workshop where the study will be explained and potential challenges and solutions discussed. In addition, the study design will be presented to the National and Provincial Male Circumcision Taskforces in order to obtain feedback. We will also seek approval from the research ethics committees at Kenyatta National Hospital and at the University of North Carolina at Chapel Hill. The study will not begin until formal approval from these research ethics committees has been obtained.

8.3 Protecting privacy and confidentiality

Research Assistants, VMMC service providers and data staff will be trained to ensure privacy during the data collection and consenting process. Data collection tablet computers will be stored at IRDO offices in Kisumu, which will be the operating headquarters of the study, and they will be password protected. The data will be accessible only to the Data Manager, the PI, and Investigators. Participants will be given contact information of KNH-ERC and the UNC IRB on the consent which they can refer to in case they want to report any violationof their rights or if they have any other study-related questions or concerns. The IRBs and the funding organization may also have access to the data and study records to review for quality and compliance with ethical standards; however, they will not have direct contact with study participants except when contacted by a participant to report a concern.

All study data will eventually be stored on a secure server to be hosted by the Carolina Population Center (CPC) atUNC-Chapel Hill. Access to the relevant datasets on the CPC server will be limited to research team members, who will be required to log in on authorized computers at CPC with their passwords.

8.4 Potential Risks of Proposed Research to study subjects

The baseline questionnaire contains some personal questions, such as discussing circumcision and sexual behavior. However, the questionnaires will be administered individually and in private. Responses given by an individual will not be shared with a partner or anyone else. This will be explained clearly during the consenting process.

This intervention may be perceived as coercive if the food voucher provides a “gain” from getting circumcised. This may occur if men enrolled in the study have their own transportation to clinic or do not face the prospect of losing income during the post-circumcision period. We have devoted considerable attention to whether this is likely to happen by discussing the intervention with community members and local officials. Prior studies have also documented that for many men above the age of 25 years, transport costs and lost work is a barrier to uptake of circumcision.

We expect the risk of coercion to be limited for several reasons. First, in the age group that has been selected (25-49) many men are engaged in some form of work (on their own farm or in off-farm labor) – not being able to do such work in the 3 days following the circumcision procedure would have economic consequence. Second, we have chosen study areas that are rural and thus it is likely to be the case that men will incur some transport costs in order to visit the VMMC clinic.Third, voucher values were selected based on documented out of pocket costs associated with getting circumcised; especially transportation and income loss associated with taking time off from work for the procedure and recovery. Finally, the minimum wage in Kenya is 412 Kenya Shillings per day, which is slightly more than what we are proposing as wage lost per day (excluding transport cost). Based on these considerations and in consultation with community members, it was decided that food vouchers valuing either KES 700 or KES

1,200 would be appropriate, given the sensitive nature of the intervention and men's concern with feeding their families.

Since the primary objective of the intervention is to increase male circumcision, those who do get circumcised may experience discomfort or pain from the procedure. We expect the risk of pain or discomfort to be infrequent. However, it is important to emphasize that this study's objective is to increase uptake of existing circumcision services and *not to provide these services.* Participants who experience any adverse events related to their circumcision will be expected to seek treatment as per the Kenya national guidelines of male circumcision.

8.5 Potential benefits of proposed research to study subjects and others

All participants will benefit from fact sheets promoting the availability of VMMC services. In addition, during enrollment, they will have a chance to ask questions and get answers from the Research Assistants. They will be informed during the consenting process that the information obtained from them will help the government of Kenya in getting older men to take up VMMC.

A central question that governments and policy makers are facing with regard to the goal of reducing the number of new HIV infections is how to effectively scale-up prevention interventions that are known to be effective. Adult male circumcision has been shown to reduce the risk of HIV infection by over 50 percent, but many HIV-affected countries are struggling to successfully scale-up circumcision coverage, particularly among men above the age of 25 years. Finding supply- and demand-side interventions is thus a priority. This study will help us understand whether in-kind compensation can help to overcome two identified barriers to uptake of male circumcision: time and transport costs related to surgery and time at work lost, due to post-procedure recovery. Several donor agencies that support the scale-up of VMMC services are looking for ways to increase demand; if successful, this study may provide a new strategy for increasing uptake of these services.

Results from the proposed study will inform programs currently implementing VMMC programs of the need to mount activities that would appeal to older men and also meaningfully involve female partners in decisions around VMMC. The results will be shared with study participants and with various stakeholders in relevant forums, such as the national and provincial VMMC task-forces, and local and international meetings and conferences. In addition, findings will be shared through publications in refereed journals

9 DATA COLLECTION AND MANAGEMENT

9.1 Data Collection

At baseline, data on circumcision status, sexual behavioral practices and related risky behaviors will be collected. These data have previously been collected in surveys in the study region and have been found to be acceptable. Research assistants will receive training at the beginning of the study on how to ask these questions and on the importance of ensuring privacy and confidentiality.

Trained research assistants will directly enter the listing of eligible adults in the selected study communities and the baseline interview into an electronic database. All study computers and records will be stored in a secure room with access limited only to authorized staff. All computers and databases will be password-protected with limited access. Daily backup of the data will be done by a designated study staff onto a server at UNC-Chapel Hill. Identifying variables will be stored in a separate dataset that will be kept on a separate password-protected computer and will also be uploaded to a server at UNC-Chapel Hill.

9.2 Data storage and security

All data will be stored on a secure server hosted by the Carolina Population Center (CPC) at UNC-Chapel Hill.The analysis of the quantitative data will be led by CPC, and CPC will also be the data coordinating center for the study. However, it should be emphasize that researchers in Kenya and elsewhere will be able to access and analyze the de-identified data with permission from the study investigators. Access to the datasets with identifying information will be limited to study investigators, who will be required to log-in on authorized computers with their passwords.

At the clinics we will record the voucher numbers and client information for men who were enrolled in the study. These will be entered into an electronic database by a study data clerk.

For the qualitative study, tape recorders and notebooks will be used to record information provided by participants and these data will be analyzed using relevant qualitative research software.

The dataset will be maintained on a secure server that is encrypted and password-protected.. The identifying information will be maintained for a maximum of five years after which they will be deleted from the servers. Any hard copies with identifying information will be stored at IRDO in locked file cabinets for one year, after which they will be destroyed. De-identified electronic datasets will be stored for a period of five years, after which they will be deleted from computers and servers.

At the conclusion of the study, audio-recordings of the qualitative interviews will be kept in a secure location for one year at IRDO. Electronic versions of transcripts, which will not contain any information identifying the individual participant, will be kept on password protected computers at FHI 360 headquarters in the United States. After one year the recordings will be destroyed.

10 STATISTICAL CONSIDERATIONS

10.1 Sample Size Justification

Power calculations were performed using the sampsi command in Stata version 12.1. These calculations suggest that with 10% uptake within 2 months of enrollment in the reference group that receives no conditional economic compensation, a sample size of 375 men per group will provide adequate power to conduct pair-wise comparisons. There will be 90% power to detect a difference in uptake as small as 9% and 80% power to detect a difference in uptake as small as 7%. With 20% uptake of VMMC in the reference group, there will be 90% power to detect a difference in uptake as small as 11% and 80% power to detect a difference in uptake as small as 9%. Statistical power will be even larger if we compare both intervention groups to the control group. We will also conduct sub-analyses to see if uptake was greater by SES or occupation.

10.2 Statistical Analysis

The main aim of this study is to measure the difference in uptake of male circumcision in the two intervention groups, compared to each other and to control. If characteristics of the control and two intervention groups are similar, then an ANOVA or multiple *t*-tests with a correction for multiple comparisons can be calculated to compare the percent of men enrolled who came to the clinic within 2 months.

Qualitative data will be analyzed on an ongoing basis as it is collected. All data will be in text format and the results will be descriptive. Data will be analyzed by the FHI 360 team using QSR NVivo qualitative data analysis software program to organize, code, and analyze qualitative data. Site staff from IRDO will also be involved in data analysis. The codebook will include deductive codes generated from the data collection instruments and inductive codes created from emerging data.

After the initial set of transcripts is prepared and reviewed by FHI 360 and IRDO, conference calls will be held to discuss patterns and trends in the data. This will provide an opportunity to make adjustments in the qualitative data analysis activities before data are fully analyzed.

11 STUDY TIMELINE

The total period planned for the project is a total of 15 months, as outlined in the table below:

	2012			2013											
	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
Protocol Development& IRB Review	X	X	X	X											
Household enumeration					X	X									
Train data collectors					X	X									
Study recruitment and enrollment						X									
Randomizeintervention						X	X	X							
Data collection and follow-up								X	X	X	X				
Qualitative follow-up interviews								X	X	X	X	X			
Data cleaning												X			
Data analysis													X	X	
Writing and presentation of results													X	X	
Disseminate results														X	X

12 ROLES AND RESPONSIBILITIES

The study is being carried out by Dr. Harsha Thirumurthy of Carolina Population Center (CPC) at the University of North Carolina at Chapel Hill, in coordination with Dr. Kawango Agot at the Impact Research and Development Organization (IRDO). Drs. Ohaga Spala and Eunice Omanga, both from IRDO and in-charge of programs and research, respectively, will work with Dr. Kawango to ensure qualitydata are collected, that ethical standards are adhered to, and that data entry and submission is done in a timely manner.

Researchers from FHI 360 (Dr. Emily Evens and Ms. Michele Lanham) will be responsible for the qualitative study that will assess perceptions of the intervention among men and women in Nyando District. The researchers have previously conducted a qualitative study on the barriers and facilitators to VMMC uptake in Nyanza Province and are well-suited to carry out the qualitative study.

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